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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/579,988	08/08/2006	Warren J. Leonard	252024	4910

45733            7590            07/11/2007  
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[REDACTED] EXAMINER

LEAVITT, MARIA GOMEZ

[REDACTED] ART UNIT      [REDACTED] PAPER NUMBER

1633

[REDACTED] MAIL DATE      [REDACTED] DELIVERY MODE

07/11/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/579,988	LEONARD ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Maria Leavitt	1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 19 May 2006.
- 2a) This action is FINAL.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 5-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) 5-31 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____.                                     |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____.   | 6) <input type="checkbox"/> Other: _____.                         |

*DETAILED ACTION*

Election/Restrictions

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

- I. Claims 5, 6, 8, 13-17 and 20 drawn to a method for enhancing an immune response in a subject comprising contacting a population of cells with IL-21 *in vivo*, then isolating one memory B cell and plasma cell and then introducing said memory B cell and plasma cell into the subject, thereby enhancing an immune response.
- II. Claims 5, 7, 9-12, 18-20 drawn to a method for enhancing an immune response in a subject comprising contacting a population of cells with IL-21 *ex vivo*, then isolating one memory B cell and plasma cell and then introducing said memory B cell and plasma cell into the subject, thereby enhancing an immune response..
- III. Claims 21-24, drawn to a method identifying an agent with a physiological effect on differentiation of one or more of a memory B cell and a plasma cell.
- IV. Claims 25-29, drawn to a method identifying an agent that inhibits an activity of IL-21.
- V. Claims 30-31, drawn to a method of inducing differentiation of a B cell progenitor.

The inventions listed as Groups I, II, III, IV and V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical reasons:

Art Unit: 1633

37 CFR 1.475 (c) states:

"If an application contains to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present"

37 CFR 1.475 (d) also states:

"If multiple products, processes of manufacture, or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT article 17(3)(a) and 1.476(c)".

The inventions listed as Groups I, II, III, IV and V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical reasons: the technical feature linking groups I, II, III, IV and V appears to be that they all relate to a method for inducing differentiation of a B cell progenitor cell into a memory B cell and/or plasma cell comprising contacting a population of cells including a mature B cell or a B cell progenitor with an effective amount of IL-21, and isolating memory B cells or plasma cells. However, prior art has described the effect of contacting IL-21 on the proliferative responses of one or more of a mature B cell and a B cell progenitor (Parrish-Novak et al., Nature 408: 57-63, 2000). Therefore, the technical feature linking the invention of groups I, II, III, IV and V does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over prior art for the reasons set forth above.

The inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical reasons:

Art Unit: 1633

A method for enhancing an immune response in a subject comprising contacting a B cell population *in vivo* with IL-21 as claimed in Group I is functionally different from the method claimed in Group II wherein the contacting of a B cell population takes place *ex vivo*. For example, contacting B cell *ex vivo* with IL-20 does not require determination of a mode of administration of IL-21 to a human subject so as to induce sufficient contact of IL-21 with a B cell population. Hence invention of Group I and Group II are drawn to methodologies with different modes of operation, each being used in different capacities, having different functions and producing different effects. Moreover, the invention of Group V, drawn to a method of inducing differentiation of a B cell progenitor, involves antigen presentation by an antigen presenting cell (e.g., macrophage, dendritic cell, Langerhan cell) whereas a method of enhancing an immune response in a subject of Group I involves activation of the humoral or cell mediated immunity with induction of a complex number of pathways. The methodology of Group V is not coextensive to the methodology of Group I. Because these inventions are distinct for the reasons given above, and are separately classified and searched, it would be unduly burdensome for the examiner to search and examine all of the subject matter being sought in the presently pending claims, and thus, restriction for examination purposes as indicated is proper.

Species restriction

Should group II be elected, a species restriction is further required under 35 U.S.C. 121 and 372, wherein a species election(s) must correspond to an elected group as indicated above.

1) A cell antigen as recited in **claim 11**, selected from one of the following molecules:

- i) a viral antigen,

Art Unit: 1633

ii) a bacterial antigen,

iii) a parasite antigen,

The species are independent or distinct because there are methods comprising **antigenic molecules** having different chemical structures, physical properties, and biological functions as a result of containing different chemical compounds or expressed genes. For example, antibodies raised against an influenza HA would not neutralize the epitope of a parasite antigen (e.g., parasitic worm (helminth) infections). Thus, the combined features of a particular species, distinct structurally and functionally, would not necessarily overlap with one another when a prior art search is conducted.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least 5 is generic.

Should group V be elected, a species restriction is further required under 35 U.S.C. 121 and 372, wherein a species election(s) must correspond to an elected group as indicated above.

2) A specifically named activated molecule as recited in **claim 30**, selected from one of the following:

i) JAK1,

ii) JAK3,

iii) STAT5A, and

iv) STAT5B.

Art Unit: 1633

The species are independent or distinct because there are methods comprising **activated molecules** having different chemical structures, physical properties, and biological functions as a result of containing different chemical compounds or expressed genes. The Janus kinase (JAK) family of tyrosine kinases (e.g., JAK1 and JAK2) and activator of transcription (e.g., STAT5) can be regulated by different mechanisms independently. For example, in the human IM-9 lymphocyte, both JAK1 and JAK2 are tyrosine-phosphorylated in response to IFN gamma, whereas only JAK2 is tyrosine-phosphorylated in response to GH whereas Stat5a and Stat5b are negatively controlled by CIS/SOCS/SSI family proteins. Thus, the combined features of a particular species, distinct structurally and functionally, would not necessarily overlap with one another when a prior art search is conducted.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least 30 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

Art Unit: 1633

the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria Leavitt whose telephone number is 571-272-1085. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300.

Art Unit: 1633

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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PRIMARY EXAMINER

